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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/680,240 | 10/08/2003 | Darwin Eton | 4052-112 | 5834 |

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| EXAMINER | |
|---|---|
| PRONE, CHRISTOPHER D | |
| ART UNIT | PAPER NUMBER |
| 3738 | |

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/680,240 | ETON, DARWIN | |
| | Examiner | Art Unit | |
| | Christopher D. Prone | 3738 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *17 January 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-4,7-12 and 15-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-12 and 17* is/are rejected.

7)☒ Claim(s) *15 and 16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *12/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The rejection over claim 8 over 35 U.S.C. 112 second paragraph has been withdrawn. In regards to the applicant's arguments that this rejection was incorrect and that the term DACRON has been used in at least 264 US Patents in the last 30 years the examiner would like to refer the applicant to See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polyester material and, accordingly, the identification/description is indefinite.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) The invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 17 is rejected under 35 U.S.C. 102(e) as being anticipated by McDermott et al (USPN 6,312,462).

With reference to Figures 1 and 2, McDermott discloses an endovascular device 10 for bridging a region of a blood vessel comprising a first, outer graft wall structure 36, said outer graft wall 36 is expandable (3:7-28) to conform to an interior shape the vessel in which it is deployed. The device further comprises an inner graft wall structure comprising a stent that is inserted after the outer wall structure has been delivered and secured (abstract lines 14-16), having proximal and distal ends, formed of a flexible elastic material that is expandable, and a means 38 for solidifiable fluid to flow to an area 32 between said outer graft wall structure 36 and inner graft wall structure 34, thereby expanding said outer graft wall (4:1-27). Means 38 may comprise a catheter in communication with a space 32 between said inner and outer graft walls and sealed with respect to said inner and outer graft walls for selectively filling said space (4:1-27). McDermott further provides the method of repairing of an aneurysmic region of a blood vessel with an endovascular device.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 7-12, are rejected under 35 U.S.C. 103(a) as being unpatentable over McDermott in view of Yannas (USPN 4,902,289).

With reference to Figures 1 and 2, McDermott discloses an endovascular device 10 for bridging a region of a blood vessel comprising a first, outer graft wall structure 36 having proximal and distal ends, said outer graft wall structure 36 being formed of a flexible, elastic polytetrafluroethylene material that is expandable (3:7-28) to conform to an interior shape the vessel in which it is deployed. The device further comprises an inner graft wall structure 34 having proximal and distal ends, at least one stent structure (5:65-6:15) secured to at least one of said inner and outer wall structures for supporting and securing the device to the vessel, and a means 38 for solidifiable fluid to flow to an area 32 between said outer graft wall 36 and inner graft wall 34, thereby expanding said outer graft wall structure and spacing said outer graft wall structure from said inner graft wall structure (4:1-27). With reference to Figures 8 and 9 the stent structures are provided adjacent proximal and distal ends of said respective walls. Means 38 may comprise a catheter in communication with a space 32 between said inner and outer graft walls and sealed with respect to said inner and outer graft walls for selectively filling said space (4:1-27). McDermott further provides the method of repairing of an aneurysmic region of a blood vessel with an endovascular device. The delivery of the outer and inner graft structures are performed simultaneously with the inner wall disposed concentrically within the outer wall.

McDermott, as discussed above, discloses the endovascular graft and method of delivering the graft as claimed. McDermott however fails to disclose that the inner graft wall comprises knitted polyester that is permeable to blood.

Yannas teaches a multi-layer graft with multiple layers (7:43-49) that has a knitted polyester (5:6-13) inner layer that is permeable to blood components (6:25-38) to provide a thromboresistant conduit with mechanical properties that match those of the adjacent natural blood vessel (abstract, 2:7-43).

Therefore in view of the teachings it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the endovascular graft as disclosed by McDermott by incorporating an inner layer comprising a knitted polyester that is permeable to blood. The motivation is evident because McDermott teaches the use of polymers or hardening agents that harden or gel from exposure to enzymatic conversion or temperature changes and by incorporating the permeable inner graft structure as taught by Yannas, the graft layer will cause more exposure of the hardening agent to the warm blood causing the hardening agents to expand more uniformly enhancing the mechanical properties and further preventing thrombosis.

## ***Allowable Subject Matter***

Claims 15 and 16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

## *Response to Arguments*

Applicant's arguments with respect to claim 17 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 1/17/06 have been fully considered but they are not persuasive.

Applicant argues that McDermott fails to disclose at least one stent structure for supporting and securing the respective wall with respect to the blood vessel. However McDermott clearly discloses supporting stent structure. The stent structure is made up of rods 46, which are described in column 5 on lines 54-64. The applicant further argues that these rods cannot support the device. However these rods maintain the shape and size by straightening and stiffening the device, which allows it to retain its position within the vessel. The applicant goes on to argue that because there is no circumferential attachment of the stiffening devices to one another they cannot perform the function of securing the wall to the blood vessel. However the graft layers provide a circumferential attachment, and further more each separate rod fully provides a stiffening support force, which retains the device in the blood vessel.

The applicant argues that McDermott teaches away from having a permeable inner layer because of its use of toxic hardening/gelling agents. The applicant cites column 4, lines 27-56 for support for this argument. The examiner would like to refer the applicant back to column 4 on lines 44-53, wherein McDermott recites preferred use of hardening/gelling materials that are nontoxic. The applicant further argues that Yannas does not teach or suggest the use of a means for a fluid to flow to an area between the inner and outer graft walls. However the rejection uses the porous graft wall as taught by Yannas. Yannas teaches use of this wall for allowing fluids including blood to flow through. The advantage and reason for combining these two references s to provide a porous inner wall, which will allow for the gel/hardening material to be fully contacted by fluids thereby ensuring complete gelling or hardening. This combination will also allow for ingrowths allowing the vessel to better accept the implant. The applicant further argues that Yannas does not teach that the permeable wall will allow whole blood to pass. However Yannas teaches that blood constitutes do pass through and the claim only requires that the wall is permeable to blood.

In regards to the applicant's comments about a lack of interview, the examiner would like to apologize for the inconvenience, but due to multiple factors a meeting time could to be established for an interview. Should the applicant still desire an interview he is encouraged to call the examiner.

## ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Prone whose telephone number is (571) 272-6085. The examiner can normally be reached on Monday Through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher D Prone
Examiner
Art Unit 3738

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SUPERVISORY PATENT EXAMINER
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CDP
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